

2015-1918

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**United States Court of Appeals  
for the Federal Circuit**

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BECTON, DICKINSON AND COMPANY,  
Plaintiff-Appellant,

v.

BAXTER INTERNATIONAL, INC.,  
Defendant-Appellee.

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Appeal from the United States District Court for the Western District of Texas  
in Case Nos. 1:14-cv-00222-LY, Judge Lee Yeakel

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**BRIEF OF APPELLANT BECTON, DICKINSON AND COMPANY**

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October 13, 2015

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

Becton, Dickinson and Company v. Baxter International, 2015-1918

**CERTIFICATE OF INTEREST**

Counsel for Becton, Dickinson and Company hereby certifies the following:

1. The full name of every party or amicus represented by me is:

Becton, Dickinson and Company

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Not applicable.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

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## **TABLE OF CONTENTS**

|  |            |
|--|------------|
| <b>CERTIFICATE OF INTEREST .....</b>   | <b>i</b>   |
| <b>TABLE OF CONTENTS .....</b>   | <b>ii</b>  |
| <b>TABLE OF AUTHORITIES .....</b>  | <b>iv</b>  |
| <b>STATEMENT OF RELATED CASES.....</b>   | <b>vii</b> |
| <b>JURISDICTIONAL STATEMENT.....</b>   | <b>1</b>   |
| <b>STATEMENT OF THE ISSUES.....</b>  | <b>1</b>   |
| <b>STATEMENT OF THE CASE.....</b>  | <b>2</b>   |
| I.    PRELIMINARY STATEMENT .....  | 2          |
| II.   PROCEDURAL HISTORY .....   | 5          |
| III.  FACTUAL BACKGROUND.....  | 6          |
| A.    The '887 Patent .....  | 6          |
| B.    Telepharmacy Before and After the '887 Patent .....  | 14         |
| 1. <i>The 2001 Texas Pharmacy Code</i> .....   | 14         |
| 2. <i>Dr. Alexander's Pilot Project and the Subsequent Amendments to the Texas Pharmacy Code</i> ..... | 18         |
| IV.  THE DISTRICT COURT'S SUMMARY JUDGMENT ORDER .....   | 20         |
| <b>SUMMARY OF THE ARGUMENT .....</b>   | <b>23</b>  |
| <b>STANDARD OF REVIEW .....</b>  | <b>25</b>  |
| <b>ARGUMENT.....</b>   | <b>27</b>  |
| I.    THE DISTRICT COURT ERRED BY ENTERING SUMMARY JUDGMENT OF INVALIDITY UNDER § 101 .....            | 28         |

|                        |   |           |
|------------------------|---|-----------|
| A.                     | The Claims are Not Directed to an Abstract Idea.....  | 32        |
| B.                     | The Claims Recite a Sufficient Inventive Concept.....   | 37        |
| 1.                     | <i>The Claims are Replete With Meaningful Limitations Above and Beyond the Purported Abstract Idea.....</i>   | 38        |
| 2.                     | <i>Remote Supervision and Verification of Pharmacy Functions, Especially Sterile Compounding, is Not a Conventional Activity in the Pharmacy Field.....</i> | 41        |
| 3.                     | <i>Using Existing Technology to Perform the Method Does Not Defeat Patent Eligibility .....</i>   | 46        |
| 4.                     | <i>No Separate Analysis for Each Disputed Claim was Conducted by the District Court to Support the Invalidity Judgment .....</i>                            | 52        |
| <b>CONCLUSION.....</b> |   | <b>55</b> |
| <b>ADDENDUM.....</b>   |   | <b>57</b> |

## TABLE OF AUTHORITIES

### *CASES*

|  |                |
|--|----------------|
| <i>Accenture Global Servs. v. Guidewire Software, Inc.</i> ,<br>728 F.3d 1336 (Fed. Cir. 2013).....                  | 26, 35, 46     |
| <i>Ala. Farm Bureau Mut. Cas. Co. v. Am. Fid. Life Ins. Co.</i> ,<br>606 F.2d 602 (5th Cir. 1979).....               | 26             |
| <i>Alice Corp. Pty. Ltd. v. CLS Bank Int’l</i> ,<br>134 S. Ct. 2347 (2014) .....                                     | <i>passim</i>  |
| <i>Anderson v. Liberty Lobby, Inc.</i> ,<br>477 U.S. 242 (1986) .....  | 26, 46         |
| <i>Bancorp Services v. Sun Life</i> ,<br>687 F.3d 1266 (Fed. Cir. 2012).....   | 35             |
| <i>Bilski v. Kappos</i> ,<br>561 U.S. 593 (2010) .....   | 35, 42, 45, 47 |
| <i>buySAFE, Inc. v. Google, Inc.</i> ,<br>765 F.3d 1350 (Fed. Cir. 2014).....  | 35             |
| <i>Content Extraction &amp; Transmission, LLC v. Wells Fargo Bank, N.A.</i> ,<br>776 F.3d 1343 (Fed. Cir. 2014)..... | <i>passim</i>  |
| <i>CyberFone Sys., LLC v. CNN Interactive Group, Inc.</i> ,<br>558 Fed. Appx. 988 (Fed. Cir. 2014) .....             | 35             |
| <i>DDR Holdings, LLC v. Hotels.com, L.P.</i> ,<br>773 F.3d 1245 (Fed. Cir. 2014).....                                | 27, 28, 36, 52 |
| <i>DealerTrack, Inc. v. Huber</i> ,<br>674 F.3d 1315 (Fed. Cir. 2012).....   | 33, 35, 37, 52 |
| <i>Diamond v. Diehr</i> ,<br>450 U.S. 175 (1981) .....   | <i>passim</i>  |

|   |                |
|---|----------------|
| <i>Digitech Image Techs., LLC v. Electronics for Imaging, Inc.,</i><br>758 F.3d 1344 (Fed. Cir. 2014).....                | 35             |
| <i>Ineos USA LLC v. Berry Plastics Corp.,</i><br>783 F.3d 865 (Fed. Cir. 2015).....                                       | 25             |
| <i>Intellectual Ventures I LLC v. Capital One Bank (USA),</i><br>2015 U.S. App. LEXIS 11537 (Fed. Cir. July 6, 2015)..... | 35             |
| <i>KSR Int’l Co. v. Teleflex, Inc.,</i><br>550 U.S. 398 (2007) .....  | 30, 48         |
| <i>Mayo Collaborative Svcs. v. Prometheus Labs.,</i><br>132 S. Ct. 1289 (2012) .....                                      | <i>passim</i>  |
| <i>OIP Techs., Inc. v. Amazon.com, Inc.,</i><br>788 F.3d 1359 (Fed. Cir. 2015).....                                       | 26, 35         |
| <i>Parker v. Flook,</i><br>437 U.S. 584 (1978) .....  | 47             |
| <i>Planet Bingo, LLC v. VKGS LLC,</i><br>576 Fed. Appx. 1005 (Fed. Cir. 2014) .....                                       | 20             |
| <i>Shelcore, Inc. v. Durham Indus.,</i><br>745 F.2d 621 (Fed. Cir. 1984).....   | 53             |
| <i>Triple Tee Golf, Inc. v. Nike, Inc.,</i><br>485 F.3d 253 (5th Cir. 2007).....  | 26             |
| <i>Ultramercial, Inc. v. Hulu, LLC,</i><br>722 F.3d 1335 (Fed. Cir. 2013).....  | 27, 32, 35, 46 |
| <i>Versata Dev. Group, Inc. v. SAP Am., Inc.,</i><br>2015 U.S. App. LEXIS 11802 (Fed. Cir. July 9, 2015).....             | 35             |
| <i>WildTangent, Inc. v. Ultramercial, LLC,</i><br>134 S. Ct. 2870 (2014) .....  | 27             |

***STATUTES***

|                             |               |
|-----------------------------|---------------|
| 28 U.S.C. § 1338(a) .....   | 1             |
| 28 U.S.C. § 1331 .....      | 1             |
| 28 U.S.C. § 1295(a)(1)..... | 1             |
| 28 U.S.C. § 2107(a) .....   | 1             |
| 35 U.S.C. § 101 .....       | <i>passim</i> |
| 35 U.S.C. § 102.....        | 47            |

***RULES***

|  |    |
|--|----|
| Federal Rule of Appellate Procedure 4..... | 1  |
| Federal Rule of Civil Procedure 56 .....   | 26 |

**STATEMENT OF RELATED CASES**

No other appeal in or from this same civil action was previously before this Court or any other court of appeals.

The patent-in-suit is the subject of a pending *inter partes* review proceeding initiated by Defendant-Appellee in the Patent Trial and Appeal Board of the U.S. Patent & Trademark Office, in Case No. IPR2015-00883.

Becton, Dickinson and its undersigned counsel are unaware of any other actions now pending in this or any other court that may directly affect or be directly affected by this Court's decision in the present appeal.

## **JURISDICTIONAL STATEMENT**

This is an appeal from the district court's final order and accompanying judgment, dated August 3, 2015, entering summary judgment that all asserted claims of U.S. Patent No. 8,374,887 are invalid. The district court had original jurisdiction under 28 U.S.C. §§ 1331, 1338(a). Becton, Dickinson and Company filed a timely notice of appeal under 28 U.S.C. § 2107(a) and Federal Rule of Appellate Procedure 4. This Court has jurisdiction under 28 U.S.C. § 1295(a)(1).

## **STATEMENT OF THE ISSUES**

1. Whether the district court erred by entering summary judgment that claims reciting methods for remotely supervising and verifying sterile compounded pharmaceuticals, and including various specific hardware and software tools for performing the methods, were directed to patent-ineligible abstract ideas.
2. Whether the district court erred by entering summary judgment of invalidity despite unrebutted evidence showing that the claimed methods recite activities that are not conventional in the pharmacy field.
3. Whether the district court erred by failing to separately analyze all claims it held invalid for patent eligibility, given that the parties presented distinct arguments directed to different claims.

## **STATEMENT OF THE CASE**

### **I. PRELIMINARY STATEMENT**

This is a case about a method that improves quality control for sterile compounding of pharmaceuticals. This is not a case about a fundamental economic process, a method for doing business, a process for organizing or manipulating data, or any other subject matter this Court or the Supreme Court has ever deemed ineligible for patent protection.

The patented methods enable a pharmacist to monitor a non-pharmacist's technical work in preparing sterile compounded medications even if the pharmacist is off-site and thus unavailable to directly monitor the work. Because the methods are designed to ensure that sterile compounded medications have been correctly prepared, implementing the claimed methods solves a problem specifically arising in this specialized area of the pharmacy field.

The claims on appeal are replete with substantial structural limitations and process steps that limit the scope of the invention to, *inter alia*, capturing images of “sterile compounding” by “a non-pharmacist person” “as the work is being performed.” Those images are transmitted to a pharmacist who is “remote” in time and/or place to review and verify that the medication has been prepared correctly. Using custom “verification software,” the pharmacist conducts the necessary supervision, verifies the steps of the preparation, and notifies the

pharmacy if the medication was prepared correctly and can be placed into pharmacy stock. With these many specific limitations for how the method is implemented, the claimed invention is not “abstract” in any sense of the word.

Yet the district court overlooked essentially all of the claim language and viewed the claims as directed to the bare idea of “supervision and verification.” Based on an assumption that the patented method can be performed using existing computer, network, and camera technology, the district court concluded that nothing in the claims narrowed their scope beyond the concept of “supervision and verification.” But the inquiry regarding patent-eligible subject matter does not turn on whether each component used to practice the invention is novel, and any eligibility analysis must examine whether the claim elements reflect an inventive concept “as an ordered combination” under the Supreme Court’s seminal *Alice* decision. This “inventive concept” analysis is not an inquiry into the novelty or nonobviousness of the invention—it is a determination of whether the claims as a whole are directed to something other than the mere purported idea of “supervision and verification.” The key question in that respect for this appeal is whether the claimed computer, camera, and network elements, alone or in combination, are used in the claimed method in a manner that was demonstrably conventional in the pharmacy field.

Here, the district court completely ignored considerable and unrebutted evidence presented to show that the claimed use of the computer, camera, and network technology in the patented method reflected anything but a conventional practice in the pharmacy field. The evidence showed that the patented method was decidedly innovative, as determined by the Texas Pharmacy Board in 2005 when it launched a pilot project proposed by Dr. Emily Alexander, the inventor of the patent-in-suit. This strongly refutes any suggestion that the method employed only conventional pharmacy activities. Following the success of that pilot project, the Texas pharmacy regulations were amended in 2008—years after the '887 Patent was filed—to permit remote supervision and verification of sterile compounding for the very first time. Ironically, despite this unrebutted evidence of Dr. Alexander pushing the boundaries of telepharmacy in Texas, the 2001 version Texas Pharmacy Code—which did not allow remote supervision and verification of sterile compounding because it pre-dated the 2008 amendment—was the sole evidence cited anywhere in the district court proceedings to attempt to show that remote supervision and verification of sterile compounding was a conventional activity.

Nothing in the record supports the district court's conclusion that such activities were conventional in the pharmacy field, and so the claims cannot possibly be deemed ineligible on this record. But even if something in the record

did support the district court's findings, the evidence at least presents a material question on the highly-factual issue of conventionality, making summary judgment inappropriate.

Because of the unique subject matter of this case and the numerous, substantial legal misconceptions by the district court, this appeal presents an important opportunity to provide much-needed guidance to the district courts by reaffirming the following legal principles: (1) that all claim requirements are meaningful and must be considered as part of both prongs of the *Alice* framework; (2) that the use of previously-existing technology to perform a claimed method does not defeat patent eligibility when the method itself is innovative or otherwise unconventional in the field of the invention; and (3) that the alleged conventionality of a method is an issue of material fact, not properly resolved on summary judgment in the presence of a genuine dispute, as exists in this case. Consistent application of these principles is vital to ensure that patent-eligible claims are not improvidently excluded at the § 101 threshold.

## **II. PROCEDURAL HISTORY**

Dr. Emily Alexander ("Dr. Alexander"), the named inventor and original assignee of U.S. Patent No. 8,374,887 ("the '887 Patent") brought this infringement lawsuit against Baxter International, Inc. ("Baxter") on March 13, 2014. A1000-02. Becton, Dickinson and Company ("BD") subsequently acquired

all right, title, and interest in the '887 Patent and was substituted for Dr. Alexander as plaintiff in the litigation. A0021.

The district court granted Baxter's request to file an early summary judgment motion challenging the claims of the '887 Patent under 35 U.S.C. § 101 for abstractness. A2029-30. Baxter filed its summary judgment motion, and the motion was fully briefed by the parties. A0022-23. Baxter's motion challenged all of the claims asserted by BD in the litigation—claims 1, 2, 5, 6, 7, 9, 13, 15, 16, 17, 20, 22, and 27. A2036.

A hearing on the motion was held on March 23, 2015. A0023. On August 3, 2015, the district court issued its order granting Baxter's motion, finding the claims of the '887 Patent invalid under § 101. A0002-13. Final judgment was entered accordingly. A0001. BD timely appealed to this Court.

### **III. FACTUAL BACKGROUND**

#### **A. The '887 Patent**

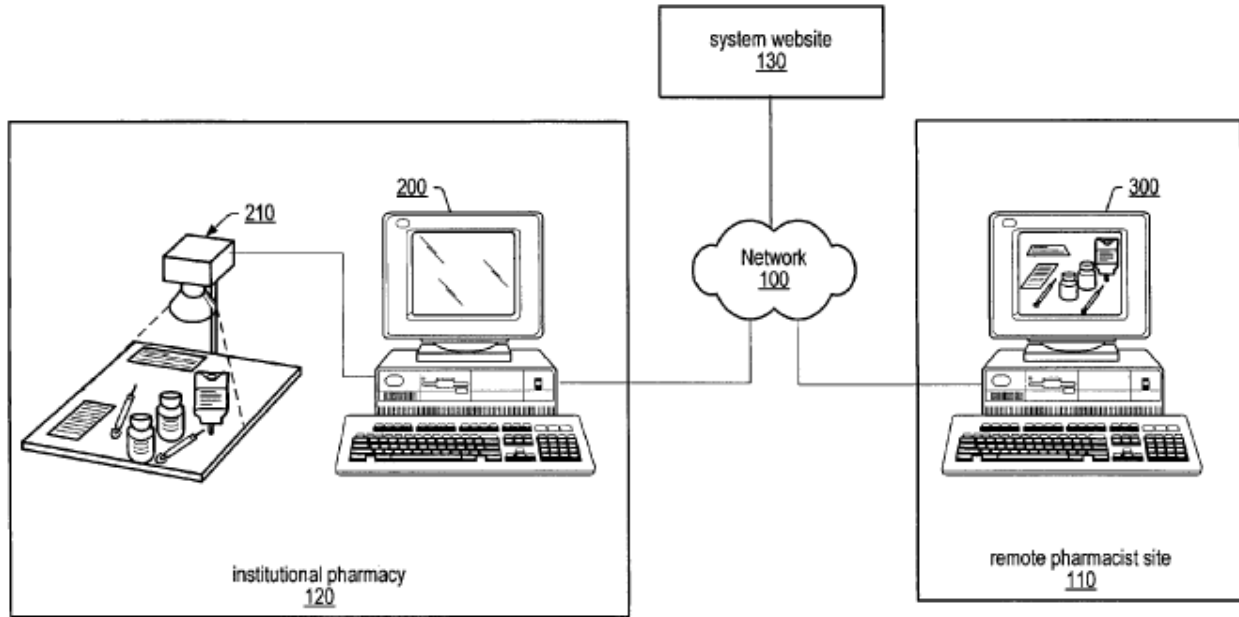
Generally, in an institutional pharmacy (such as a pharmacy in a hospital or correctional facility), any technical pharmacy function performed by a non-pharmacist person must be supervised and verified by a licensed pharmacist. '887 Patent, at 1:14-39. The '887 Patent is directed to a new method for improving the supervision and verification of a particular highly-technical pharmacy function—sterile compounding of pharmaceuticals. *See, e.g.*, '887 Patent, at Claim 1. The

claimed methods, which implement specific hardware and software functions in ways not previously done in the pharmacy field, enable the sterile compounding process to be supervised and verified by a pharmacist who is remote in time and/or place. *Id.*

The '887 Patent explains that most institutional pharmacies do not have pharmacists on duty at all times, yet patients often need medications to be prepared after hours, or when a pharmacist is otherwise unavailable. '887 Patent, at 1:40-44. In such situations, non-pharmacist personnel would enter the pharmacy, obtain the medication (by preparing it, if necessary), and provide it to the patient, all before the pharmacist returns to duty. '887 Patent, at 1:44-62. Thus, “patients may receive medication that has been prepared, packaged, compounded, and labeled without being first verified by a pharmacist.” *Id.* at 1:46-47. Although a pharmacist may “retrospectively verify that the pharmacy work was performed correctly” by confirming that the “correct medication, in the correct dose and dosage form” was used, this presents a dangerous state of affairs because the sterile compounding process to prepare the drug could not be reviewed, and so “[a]n error may thus be discovered, but not prevented by the pharmacist.” *Id.* at 1:48-50, 1:56-62. As discussed *infra*, such unmonitored sterile compounding was also against applicable pharmacy regulations.

The technical complexity of preparing sterile compounded medications highlights how dangerous a lack of proper supervision and verification can be. Such medications are typically prepared for intravenous delivery and must be made at very specific doses in a sterile environment to ensure that no foreign or particulate matter is present. *See* '887 Patent, at 9:55-10:3. This process is considerably more advanced and sensitive than counting pills or applying correct labels to prepackaged medications. The dire consequences of administering an improperly-compounded medication to a patient cannot be overstated, as the adverse health consequences to the patient can be serious or even fatal.

To address the need for better quality control, the invention disclosed in the '887 patent enables sterile compounding performed by non-pharmacists to be supervised and verified in an accurate and timely manner despite the lack of a pharmacist on-site at the time of the sterile compounding. '887 Patent, at Abstract. An exemplary embodiment of a remote supervision system is provided in Fig. 5:



As shown in Fig. 5, the system includes an image capture device (210) connected to a computer (200), which provides a sterile compounding workstation at an institutional pharmacy, such as a pharmacy at a hospital or correctional facility. *Id.* at 5:13-14, 9:55-57. The institutional pharmacy sterile compounding workstation communicates with a computer (300) at a remote pharmacist site (110) via a network (100). An image captured on the image capture device (210) at the institutional pharmacy (120) is sent and viewed at the remote pharmacist site (110) *Id.* at 9:55-57.

In operation, for example, a non-pharmacist technician at the institutional pharmacy site (120) may enter the institutional pharmacy and compound a sterile intravenous product that was ordered for a patient after pharmacy hours, when no pharmacist is on duty at the institutional pharmacy. *Id.* at 9:58-62.

While preparing the compounded sterile intravenous product, the non-pharmacist technician places the labeled sterile components on the display area of the image capture device (210). *Id.* at 9:67-10:3. One or more images are captured as the work is being performed, with each image capturing a different stage of the pharmacy work. *Id.* at 8:62-64. The captured image(s) may include information necessary for supervision and verification that the compounding process was performed correctly, such as:

1. Medication labels, solution labels, final product labels.
2. Supplies used in compounding the product.
3. Equipment indicating volumes used in product preparation.
4. Indications of the order in which medications were added during product preparation.
5. Prescriber's order including patient name, drug name, dose, route of administration, schedule of drug administration, reason for administration, and signature of the prescriber or his agent.
6. Documentation that includes drug name, strength, lot number, expiration date, date, time, number of units to be removed from the pharmacy, worker initials, worker signature and title.
7. Auxiliary labels.
8. Special storage requirements for medication.
9. Drug information references.

*Id.* at 10:45-67.

The captured image(s) are transmitted to a system website (130) via a network or telecommunication link (100), and are downloaded by a workstation at the remote pharmacist site (110). *Id.* at 10:26-39. A pharmacist at the remote pharmacist site (110) views the pharmacy work performed at the institutional pharmacy (120), as well as any other information necessary to conduct process

checks and verify that the medication in the captured image(s) was correctly and accurately compounded. *Id.* at 10:41-47. During the pharmacist's review, the pharmacist inspects the captured image(s) to observe one or more of the following: (1) that the label on the intravenous product is complete and correct according to the medication order, properly lists the base solution used during the sterile compounding process, and has been initialed by the technician; (2) that the technician added the correct diluent during the sterile compounding process; (3) that the correct medication vial was selected, and that the correct volume of the medication solution was added to the final product during the sterile compounding process; (4) that the intravenous product has a sterile seal on the port designed for addition of medication; and (5) that there is no obvious particulate matter in the solution. *Id.* at 11:21-36.

If the pharmacist at the remote site (110) discovers, through inspection of the captured images, errors in the work performed by the non-pharmacist technician, the pharmacist may notify both the non-pharmacist technician who performed the work, as well as other supervisory personnel, about the errors so that corrective measures may be taken. *Id.* at 12:32-38.

If no errors are detected, the pharmacist indicates that the work has been supervised and verified according to the captured image(s), and is authorized for removal from the pharmacy or to be placed into regular pharmacy stock. *Id.* at

11:41-45. The pharmacist may indicate that pharmacy work has been verified in any of a number of different ways, such as graphically inserting a notation into one or more of the images or electronically initialing one of the captured images. *Id.* at 11:45-52. An electronic record or a hard copy of the verified captured image(s) may be stored at the remote pharmacist site (110) and/or at the system website (130), and an indication that the pharmacist verified the pharmacy work may also be transmitted to the institutional pharmacy (120), such as via an email. *Id.* at 11:60-12:5. The medication may then be removed from the pharmacy stock and administered to the patient. *Id.* at 12:23-28.

The '887 Patent includes twenty-seven claims, of which claims 1 and 16 are in independent form. Claim 1 is reproduced below:

1. A method for remote supervision and verification of pharmacy functions that are performed by a non-pharmacist person, comprising:

in response to performance, by a non-pharmacist person, of pharmacy work to prepare a medication at an institutional pharmacy, wherein the pharmacy work requires pharmacist verification of the pharmacy work, wherein performing the pharmacy work comprises the non-pharmacist person performing, at a workstation in the institutional pharmacy, a sterile compounding process to prepare the medication, wherein the medication is compounded from a plurality of material components at the workstation within the institutional pharmacy:

capturing, via an image capture device at the workstation in the institutional pharmacy, one or more images of the pharmacy work performed by the non-pharmacist person as the work is performed by the non-pharmacist person at the institutional pharmacy, wherein at least one of the images is an image of the sterile compounding process performed by the non-pharmacist person that requires verification by a pharmacist for medications to be placed into pharmacy stock;

implementing verification software, via one or more computers at the institutional pharmacy, to remotely verify the work performed by the non-pharmacist person, wherein remote verification of the work performed by the non-pharmacist person comprises:

transmitting the one or more images captured by the image capture device of the sterile compounding process performed by the non-pharmacist person at the workstation to a remote pharmacist for review, wherein said transmitting the one or more images comprises storing the images on a website; receiving an indication of the remote pharmacist's verification of the correct performance of the sterile compounding process by the non-pharmacist person; and

providing, in response to the indication of the remote pharmacist's verification, an indication at the institutional pharmacy that the remote pharmacist has verified the sterile compounding process performed by the non-pharmacist person.

Independent claim 16, while directed to a similar method, is of a distinct scope when compared to claim 1. Claim 16 recites the elements of claim 1, except that it does not require storing images on a website, but adds the additional requirement that:

wherein capturing the one or more images comprises capturing two or more images of the sterile compounding process of the sterile compounded medications as the sterile compounded medications are prepared, wherein at least one of the two or more images is captured at a different stage of the compounding of the sterile compounded medications than at least one other of the two or more images.

The dependent claims recite still more specific implementations of the invention. Claims 2 and 17, for example, recite the particular content of the captured image(s) of the sterile compounding process as including multiple material components and “one or more measures for the material components.” Claims 15 and 27 similarly require that the remote pharmacist provides verification to the non-pharmacist

regarding the compounding “on a step-by-step basis” for at least two steps of the process.

B. Telepharmacy Before and After the '887 Patent

At the time of Dr. Alexander’s invention, telepharmacy systems neither contemplated, nor were permitted to perform, remote supervision and verification of advanced pharmacy functions such as sterile compounding. Shortly after the '887 Patent was filed in early 2005, Dr. Alexander spearheaded a pilot project in Texas to allow pharmacists to remotely supervise and verify sterile compounding performed by pharmacy technicians (i.e., non-pharmacist persons). As the evidence summarized below demonstrates, the success of this pilot project resulted in the Texas Pharmacy Code being amended to allow, for the first time, remote supervision and verification of sterile compounding.

1. *The 2001 Texas Pharmacy Code*

In Baxter’s motion for summary judgment, Baxter relied on portions of the 2001 Texas Pharmacy Code to purportedly show that the '887 Patent claims “read on earlier-enacted Texas telepharmacy statutes.” A2040. According to Baxter, because the Texas Pharmacy Code allowed for “still image capture” and “store and forward” technology in certain telepharmacy contexts, Baxter asserted that the use of such technology was routine and conventional in the field to remotely supervise and verify sterile compounding. A2042-43.

BD's response included a declaration from Dr. Roger Anderson, the former President of the Texas Pharmacy Board, who was intimately familiar with the Texas Pharmacy Code. A2408-11. Dr. Anderson explained that, prior to 2001, the Texas Pharmacy Code "required a pharmacist to directly—i.e., in person and on-site—supervise and verify all relevant pharmacy functions performed by nonpharmacist persons in all pharmacies." A2408.

In 2001, the Texas Pharmacy Code was amended to allow for limited telepharmacy activities "to allow a pharmacist located in a provider pharmacy to remotely verify the dispensing of previously prepared medications." A2409. The only medications allowed to be dispensed via telepharmacy were "prepackaged and pre-labeled in unit of use containers." A2409 (citing A2076, at § 291.20(c)(4)(D)(ii) ("Drugs may be dispensed by the provider pharmacy through a telepharmacy system at a remote site only in unit-of-use containers that are: (I) prepackaged in suitable containers at the provider pharmacy and appropriately labeled ... ; or (II) in original manufacturer's containers.'')).

Because the medications allowed to be dispensed via telepharmacy were all previously prepared by the provider pharmacy or the manufacturer, the telepharmacy system was used not to remotely determine whether the medication was properly made or compounded, but only "for the provider pharmacist to perform the *final check* of the prescription medication and authorize the printing of

a prescription label at the remote site before the medication was dispensed to the patient.” A2409 (emphasis added) (citing A2077, at § 291.20(c)(4)(D)(vi) (allowing a “visual check using electronic methods” only to confirm whether “the prescription has been dispensed accurately as prescribed”)); *see also* A2085-86, at § 291.36(b)(45)(B) (distinguishing “in-process” checks from “final” checks in institutional pharmacies, both of which are in-person under the “direct supervision of ... a pharmacist”). Nothing in the Texas Pharmacy Code ever refers to capturing images of the sterile compounding process while it is being performed, for telepharmacy purposes or otherwise. Thus, to the extent that any “image capture” or “store and forward” technology was contemplated for telepharmacy in the 2001 Texas Pharmacy Code,<sup>1</sup> it was only for a “final [visual] check” that the previously prepared medication matched the prescription, and never in the context of remotely supervising and verifying sterile compounding of the medication by capturing images as the work was performed. A2076-77, at §291.20(c)(4)(D)(ii), (vi).

Entirely different sections of the 2001 Texas Pharmacy Code address regulations for telepharmacy (§ 291.20 for “Remote Pharmacy Services”) and institutional pharmacies (§ 291.36 for “Class A Pharmacies”), respectively. *See*,

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<sup>1</sup> *See* A2072-73, at §291.20(c)(2)(I) (allowing for use of “[a] specific image captured electronically from a video or other image capture device”); A2073, at §291.20(c)(2)(J)) (allowing for use of “[a] video or still image record which is saved electronically for future review”).

*e.g.*, A2060; A2081. As demonstrated by the strict telepharmacy limits noted above, these disparate sections are subject to disparate regulatory controls and must not be conflated. Indeed, despite the 2001 telepharmacy amendments, for institutional pharmacies the Texas Pharmacy Code “still required a pharmacist to directly—*i.e.*, on-site and in person—supervise and verify pharmacy functions performed by non-pharmacist persons, including the preparation of medications and particularly the preparation of sterile compounded products.” A2409; A2091-92, at §291.36(c)(4)(B)(ii)(II) (sterile compounding may be performed by a technician only if the technician was “under the *direct* supervision of and responsible to a pharmacist”) (emphasis added); A2092, at §291.36(c)(4)(B)(iii)(IX)(-b-)(-3-) (allowing a pharmacy technician to perform “compounding sterile pharmaceuticals” provided that “the pharmacy technician is supervised by a pharmacist” who, in person, conducts both “in-process” and “final” checks).

The 2001 Texas Pharmacy Code is also very clear about what *is* permitted to be done by a non-pharmacist without direct in-person supervision. If a pharmacist is absent from the prescription department of a pharmacy, technicians can only do one of six very explicit tasks, none of which is sterile compounding. A2103-04, §291.36(d)(2)(D)(ii)(I)-(VI) (listing the tasks of “(I) initiating and receiving refill authorization requests; (II) entering prescription data into a data processing system;

(III) taking a stock bottle from the shelf for a prescription; (IV) preparing and packaging prescription drug orders (i.e., counting tablets/capsules, measuring liquids and placing them in the prescription container); (V) affixing prescription labels and auxiliary labels to the prescription container ... ; and (VI) prepackaging and labeling prepackaged drugs”). And even these tasks still require the pharmacist to verify the “functions performed by the pharmacy technicians prior to delivery of the prescription to the patient.” *Id.*

2. *Dr. Alexander’s Pilot Project and the Subsequent Amendments to the Texas Pharmacy Code*

Dr. Alexander, the sole inventor of the ’887 Patent, changed the status quo for telepharmacy in Texas in 2005. On March 21, 2005, shortly after the ’887 Patent was filed, she proposed a pilot project entitled “Evaluation of a Pharmacy Practice Model Providing Electronic Supervision of Registered Pharmacy Technicians by a Pharmacist in Small Texas Hospital Pharmacies During Absence of an On-Site Pharmacist.” A2409-10. The Texas Board of Pharmacy, including Dr. Anderson, reviewed the proposal. A2410. The board was required by statute only to approve pilot projects “for innovative applications to the practice of pharmacy which contribute to positive patient outcomes.” A2410. Dr. Alexander’s proposal was quickly deemed to meet this standard, and was approved and implemented. A2410 (citing A2422-26) (board recommendation explaining pilot program conditions for remote supervision of sterile compounding). Being a

pilot program, it was approved only for class C pharmacies in small hospitals of 100 beds or less. A2424-25.

The pilot program was completed in 2007, and a January 4, 2008 report summarized the results. A2410. Among other conclusions, the report noted that remote supervision under the program appeared to have “prevented medication errors” and made sterile compounded pharmaceuticals “available during hours previously not serviced by a pharmacist.” A2431-32.

The Texas Pharmacy Board “unanimously voted in May 2008 to amend the Texas Rules 291.72–73 to permit remote supervision and verification of pharmaceutical preparation, including sterile compounding in institutional pharmacies having 100 or fewer beds.” A2410 (citing A2441 (“[T]he suggested amendments would allow pharmacists in facilities licensed for 100 beds or less to supervise pharmacy technicians electronically.”)). The Texas Pharmacy Code was then formally amended to provide that for “[f]acilities licensed for 100 beds or less,” “[t]he following functions may be performed under the electronic supervision or physically present supervision of a pharmacist: ... (VI) compounding low-risk sterile preparations.” A2465, A2469-70; *see also* A2468-69 (providing that “compounding sterile preparations” for “[f]acilities licensed for 101 beds or more” “must be performed under the physically present supervision of a pharmacist”). As Dr. Anderson summarized,

Those amendments in 2008 reflect the first time that the Texas Pharmacy Rules allowed remote supervision and verification of pharmacy functions related to the preparation of medications and to the preparation of compounded sterile products. Thus, at least based on the Texas Pharmacy Rules and history thereof discussed above, it cannot be said that remote supervision and verification of sterile compounding was merely conventional or routine activity in the pharmacy field, let alone a longstanding or fundamental practice.

A2411. Indeed, because Dr. Alexander’s pilot project spurred the Texas Pharmacy Code to be *amended* in 2008 to *permit* remote supervision and verification of sterile compounding, it necessarily follows that remote supervision and verification of sterile compounding was not permitted by the 2001 Texas Pharmacy Code, and thus could not be deemed routine or conventional.

#### **IV. THE DISTRICT COURT’S SUMMARY JUDGMENT ORDER**

In granting Baxter’s motion for summary judgment, the district court began by treating claim 1 as “representative for the purposes of the court’s Section 101 analysis.” A0004. Finding, in a footnote, that the many dependent claims in the ’887 Patent “introduce only slight variations of the independent claims,” the court stated that it “need not consider each claim distinctly.” A0004-05 (citing *Content Extraction & Transmission, LLC v. Wells Fargo Bank, N.A.*, 776 F.3d 1343, 1348 (Fed. Cir. 2014) and *Planet Bingo, LLC v. VKGS LLC*, 576 Fed. Appx. 1005, 1007 (Fed. Cir. 2014)). Although the district court expressly noted that independent claim 16 differs from claim 1, the district court proceeded to analyze only claim 1 under *Alice*. A0005-06.

The district court concluded that the claims were directed to the abstract idea of “supervision and verification” because, in its view, “the claims do not present a concept or idea that is any more concrete than supervision and verification.” A0010. According to the district court, “[t]he fact that the pharmacist is ‘remote’ is of no added consequence to the abstract nature of the concept.” A0010.

The district court further found that “the claims use generic, off-the-shelf technology applied in a conventional way to achieve the aim of the patent.” A0011. Reasoning that “[t]he patent does not describe a novel sterile compounding process, a new type of image-capture device, or a particularized website or software program to perform any step,” the district court concluded that the claims lacked any inventive concept beyond the abstract idea of “supervision and verification.” A0012 (emphasizing that “Becton does not, and cannot, argue that the computer elements, capture device, network infrastructure, or supporting software described in the claims are in themselves new inventions.”). Accordingly, the district court granted Baxter’s motion and entered summary judgment that all of the asserted claims in the ’887 Patent were invalid for being directed to unpatentable subject matter. A0012-13 (concluding that “the patent seeks merely to apply existing technology to the abstract and arguably age-old process of supervising and verifying the work of a nonpharmacist”). At no point

did the district court separately analyze whether the elements of the method, as a whole and as an ordered combination, present an inventive concept.

Conspicuously absent from the district court's order is any mention whatsoever of the Texas Pharmacy Code or Dr. Anderson's declaration, both of which formed substantial portions of the parties' briefs and arguments. *See, e.g.*, A2400-04. BD had explained that these factual issues, at a minimum, precluded summary judgment from being entered. A2403-04. Despite the district court reciting the correct legal standards regarding proof of "the absence of a genuine issue of material fact" and "draw[ing] all reasonable inferences" in BD's favor, this evidence is not discussed, alluded to, or even cited anywhere by the district court. A0006. Although this evidence demonstrates that remote supervision of sterile compounding was far from conventional—and was, in fact, "innovative"—the district court cited exactly zero evidence for its pronouncement that "it is *inescapable* that the claims use generic, off-the-shelf technology applied *in a conventional way* to achieve the aim of the patent." A0011 (emphasis added). Several times the district court made critical findings that all trace back to this same fatal evidentiary defect. *See, e.g.*, A0011 ("The claims and specification instead teach *well-known elements used in conventional ways* combined to perform the steps of supervision and verification."); A0011-12 ("The court can find no inventive concept in any of the claim language that 'amounts to significantly more'

than a detailed description of *conventional, if generic, steps* of remotely supervising and verifying the work of a nonpharmacist who is preparing prescriptions.”) (emphases added).

### **SUMMARY OF THE ARGUMENT**

The district court’s entry of summary judgment of § 101 ineligibility was wrong and must be reversed. This case is riddled with fact issues concerning the conventionality of the claimed method steps in the relevant pharmacy industry—issues that should preclude the possibility of summary judgment outright. The district court’s judgment is also premised on legal errors applying the wrong standards for what constitutes a patent-eligible method, or otherwise misapplying the law. Both kinds of error independently negate the district court’s judgment.

The ’887 Patent claims a combination of hardware and software elements used to improve quality control for sterile compounding of pharmaceuticals. In particular, when a pharmacist is unavailable to directly (i.e., in-person and on-site) supervise sterile compounding performed by a non-pharmacist, the claimed methods ensure that the pharmacist is able to nonetheless supervise and verify the process from a remote site. The claims involve capturing one or more images of the sterile compounding process and transmitting the image(s) to the remote pharmacist for review and verification using custom verification software. This is not an abstract idea, but is a specifically-claimed tool expressly tethered to use

within a unique area of the pharmacy field. The claimed methods allow for timely and accurate supervision in this exceptionally important medicinal context, and go far beyond the mere concept of “supervision and verification,” as the district court held.

The district court found it “inescapable” that systems such as those claimed in the ’887 Patent were conventionally used in the pharmacy field to supervise and verify sterile compounding performed by non-pharmacists. But the record is not only devoid of any support for that finding, it is filled with unrebutted evidence that controverts the finding by proving that the claimed methods were innovative compared to the pharmacy regulations that Baxter proffered to allegedly show conventionality. Specifically, the evidence shows that then-applicable pharmacy regulations would not allow for any remote supervision of sterile compounding, and that the ’887 Patent’s inventor spearheaded a pilot project to test a remote supervision system for sterile compounding. That pilot project was successful, and resulted in those same regulations being amended to allow, for the first time, remote supervision for sterile compounding by non-pharmacists. The district court did not properly consider this evidence, which affirmatively proves the nonconventionality of the claimed method as a whole, and which was supposed to be viewed in the light most favorable to BD. Summary judgment of patent ineligibility was improper due to these substantial disputed issues of material fact.

The district court also erroneously insisted that each computer and software component used in performing the method be itself novel—essentially requiring BD to have reinvented the computer, the camera, and the Internet to even possibly satisfy § 101. But the Supreme Court in *Diehr* long ago jettisoned any such novelty-focused test for the eligibility of method claims, and made clear that methods for improving quality control over existing technological processes are eligible for patent protection even if they do not involve the creation of new technology components per se. Whether viewed as a new method or an improvement over existing methods, the use of existing technology for new and non-conventional purposes, and to solve a problem arising in the relevant field, suffices to overcome § 101.

Finally, the district court analyzed only the limitations of claim 1 before pronouncing 13 distinct claims ineligible for patent protection. The parties separately addressed claims other than claim 1, however, and so the judgment for those remaining claims cannot stand without a separate analysis for each disputed claim.

### **STANDARD OF REVIEW**

This Court reviews the grant or denial of summary judgment based on the law of the regional circuit where this appeal would otherwise lie—in this case, the Fifth Circuit. *Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 868 (Fed. Cir.

2015). The Fifth Circuit reviews summary judgment decisions *de novo*. *Id.* (citing *Triple Tee Golf, Inc. v. Nike, Inc.*, 485 F.3d 253, 261 (5th Cir. 2007)).

Federal Rule of Civil Procedure 56 prohibits the entry of summary judgment unless “the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” A genuine dispute of fact exists “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). As the Court is not supposed to weigh the evidence or make credibility determinations on summary judgment, “[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.” *Id.* at 255; *see also Ala. Farm Bureau Mut. Cas. Co. v. Am. Fid. Life Ins. Co.*, 606 F.2d 602, 609 (5th Cir. 1979) (“[I]nferences most favorable to the party opposing the motion will be drawn. Such inferences may create disputes regarding basic facts or regarding facts to be inferred from such facts.”) (citation and internal quotation marks omitted).

Patent eligibility under §101 is an issue of law that is reviewed *de novo*. *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362 (Fed. Cir. 2015). However, “[t]his legal conclusion may contain underlying factual issues.” *Accenture Global Servs. v. Guidewire Software, Inc.*, 728 F.3d 1336, 1341 (Fed. Cir. 2013). “Almost by definition, analyzing whether something was

‘conventional’ or ‘routine’ involves analyzing facts.” *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1339 (Fed. Cir. 2013), *vacated sub nom. WildTangent, Inc. v. Ultramercial, LLC*, 134 S. Ct. 2870 (2014).

### **ARGUMENT**

A patent may be obtained on any “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” 35 U.S.C. § 101 (2012). “Laws of nature, natural phenomena, and abstract ideas” are excluded from patentability. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355, 2359-60 (2014). However, “[a]t some level, ‘all inventions ... embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.’” *Id.* at 2354 (quoting *Mayo Collaborative Svcs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1293 (2012)). Thus, courts must “tread carefully in construing this exclusionary principle lest it swallow all of patent law.” *Id.*

In determining whether a patent claim meets the requirements of § 101, a court first determines whether the claim is directed to an ineligible idea, and, if so, whether the elements of the claim, “both individually and as an ordered combination,” add an inventive concept thereto. *Alice*, 134 S. Ct. at 2355. Under this two-part test, practical applications of abstract ideas have repeatedly been held to be patentable. *See, e.g., DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245

(Fed. Cir. 2014); *see also Diamond v. Diehr*, 450 U.S. 175, 187 (1981) (as confirmed in *Alice*, 134 S. Ct. at 2358). Claims that use computer technology to “improve[] an existing technological process,” or “overcome a problem specifically arising in the realm [of the invention]” are not precluded at the threshold from patent protection. *See Alice*, 134 S. Ct. at 2358 (discussing *Diehr*); *DDR Holdings*, 773 F.3d at 1257. The role of a computer in a computer-implemented invention need only involve more than performance of “well-understood, routine, [and] conventional activities previously known to the industry.” *Content Extraction*, 776 F.3d at 1347-48.

**I. THE DISTRICT COURT ERRED BY ENTERING SUMMARY JUDGMENT OF INVALIDITY UNDER § 101**

The invention of the ’887 Patent is directed to a specific implementation of a remote pharmaceutical supervision and verification system. The claimed methods require particular hardware components and verification software to solve a real-world technical problem arising in the pharmacy field. The claims are expressly limited, *inter alia*, to a “non-pharmacist person performing, at a workstation in the institutional pharmacy, a sterile compounding process”; “capturing ... one or more images of the pharmacy work ... as the work is performed by the non-pharmacist”; “transmitting the one or more images ... to a remote pharmacist for review” and, in one claimed embodiment, “storing the images on a website”; and using claimed “verification software” that enables a remote pharmacist to review the images of

the sterile compounding and indicate to the institutional pharmacy whether the sterile compounding was performed correctly. '887 Patent, at Claims 1, 16. The claimed processes allow pharmacies to more flexibly allocate resources for sterile compounding review and verification, as they need not be done in real-time, can be done individually or in batches, and can be distributed among one or several individuals at one or several physical locations.

This is not an “abstract” concept, and any fair reading of the claims as a whole reveals that the concept encompassed by the claims is much more concrete than merely “supervision and verification,” as the district court held. As a starting point, the claims themselves are expressly directed to “method[s] for remote supervision and verification of pharmacy functions that are performed by a non-pharmacist person,” which immediately provides considerably more specificity to the claimed subject matter. '887 Patent, at Claims 1, 16. Despite the district court’s conclusion “that the pharmacist is ‘remote’ is of no added consequence to the abstract nature of the concept” (A0010), the words “remote” and “remotely” pervade the text and meaning of the claims, significantly limiting the claims to solve a pharmacy-centric problem, and using an ordered combination of components and steps that were not previously contemplated in the field.

While the '887 Patent does not purport to have invented the computer, the camera, or the concept of a computer network for communicating information, the

district court deemed the use of “off-the-shelf” technology fatal to the question of patent eligibility. Setting aside the fact that the claimed “verification software” provides specially-programmed functionality that is not performed by an off-the-shelf computer workstation, BD need not show that these components “are in themselves new inventions,” as the district court suggested. A0012. It is enough that the use of such components, individually or as an ordered combination, for practicing the claimed invention is not well-understood, routine, or conventional in the pharmacy field. *Content Extraction*, 776 F.3d at 1348; *cf. KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418-19 (2007) (“[I]nventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.”).

BD presented ample un rebutted evidence that it was anything but “conventional” for such a remote supervision and verification system to be used in connection with sterile compounding via telepharmacy. *See supra* Statement of Facts, Part III.B. But the district court ostensibly completely ignored this evidence when proclaiming that the claims recite no inventive concept “more than a detailed description of conventional, if generic, steps of remotely supervising and verifying the work of a non-pharmacist who is preparing prescriptions.” A0011-12. The

district court's failure to even consider the evidence before it that controverts this finding is alone reversible error that precludes the entry of summary judgment.

Had the district court conducted a meaningful review of the claim steps "as an ordered combination" as *Alice* requires, this error would have been avoided. The methods recited in the '887 Patent amount to more than the sum of their individually-recited steps using individually-recited components. While the district court paid lip service to the "ordered combination" requirement of *Alice*, the substance of the court's analysis focused only on whether the components and steps of the methods "are in themselves new inventions." A0011-12 (finding that "[t]he patent does not describe a novel sterile compounding process, a new type of image-capture device, or a particularized website or software program to perform any step"). Considering the claims as a whole, and as an ordered combination, the concreteness and non-conventionality of the claims are manifestly evident, as the highly-detailed claims recite various real-world steps using specific configurations of technological tools to accomplish the resulting quality control.

Finally, by incorrectly treating claim 1 as "representative," the district court did not even attempt to support its judgment as to any of the other twelve distinct claims that it concluded are impermissibly abstract. Only claim 16's distinct limitations are even mentioned by the district court, but no reasoning is provided for why the differences between claims 1 and 16 "do not change the validity

calculus.” A0004-06. The other 11 claims are disposed of without even acknowledging the different requirements of those claims and the associated arguments made by BD to distinguish those claims from claims 1 and 16. A0004-06. This dearth of analysis is facially insufficient to establish invalidity under § 101.

Each of the foregoing issues will now be addressed in turn.

A. The Claims are Not Directed to an Abstract Idea

The Supreme Court has clearly directed that all claim elements are meaningful and must be considered as part of a § 101 analysis. *See Diamond v. Diehr*, 450 U.S. 175, 188 (1981) (“Claims must be considered as a whole.”). Because all inventions encompass abstract ideas to some extent, failing to analyze the claims “as a whole” leads to overbroad interpretations that would make *every* patent claim impermissibly abstract and frustrate the purpose of the abstractness doctrine. *See Alice*, 134 S. Ct. at 2354; *Diehr*, 450 U.S. at 187. Indeed, “any claim can be stripped down, simplified, generalized, or paraphrased to remove all of its concrete limitations, until at its core, something that could be characterized as an abstract idea is revealed. A court cannot go hunting for abstractions by ignoring the concrete, palpable, tangible limitations of the invention the patentee actually claims.” *Ultramercial*, 722 F.3d at 1344, *vacated sub nom. WildTangent*, 134 S.

Ct. 2870. Thus, “[i]n considering patent eligibility under § 101, one must focus on the claims.” *DealerTrack, Inc. v. Huber*, 674 F.3d 1315, 1334 (Fed. Cir. 2012).

Merely taking two disembodied words—“supervision” and “verification”—from the preambles of the claims of the ’887 Patent, as the district court did, fails to analyze the claims as a whole and is insufficient to demonstrate that the claims are “directed to” an abstract idea. *See Alice*, 134 S. Ct. at 2355-56; *Mayo*, 132 S. Ct. at 1304; *Diehr*, 450 U.S. at 187. The claims are replete with substantial structural elements being used in a real-world technical environment—e.g., “a non-pharmacist person performing, at a workstation in an institutional pharmacy, a sterile compounding process to prepare the medication, wherein the medication is compounded from a plurality of material components at the workstation.” The steps of the method are also directed to improving the process by which institutional pharmacies accomplish the quality control of the preparation of their sterile compounded medications. First, “as the work is being performed by the non-pharmacist person,” images of the sterile compounding process are captured. Claim 16 further recites that “two or more images” are captured, each “at a different stage of the compounding.” Once the desired images are captured, using an arrangement of computer workstations, a network, and verification software, a “remote pharmacist” is able to receive, review, and verify the accuracy of the images as they pertain to the correct sterile compounding process. An indication

of the verification is provided by the remote pharmacist, and then another distinct indication is provided at the institutional pharmacy regarding the verification. The claims even recite that verified medications are “to be placed into pharmacy stock.” Especially when compared to the many claims that have been held invalid in the wake of *Alice*, these claims are remarkably concrete.

The claims are not directed to any and all forms of “supervision and verification.” They are not directed to the mere notion of “remote supervision and verification.” They are not even directed to the mere idea of remotely supervising pharmacy functions. These claims encompass a precise and innovative use of hardware and software to accomplish a technological improvement in a specialized area of the pharmacy industry—namely, quality control of sterile compounding performed by non-pharmacist persons when a pharmacist is remote and thus unavailable to directly supervise. The claims could not be much more specific in this regard. In the claims, for example, the images captured are not unbounded or for any purpose—they are specifically recited as being “one or more images of the pharmacy work [which ‘comprises ... sterile compounding’] performed by the non-pharmacist person as the work is performed by the non-pharmacist person at the institutional pharmacy.” Claim 16 further requires “two or more images of the sterile compounding process ... [taken] at different stages.” Further, the remote

pharmacist is specified to perform the verification not for some intangible purpose, but so that the medications can be “placed into pharmacy stock.”

These claims are nothing like the many other claims this Court has deemed ineligible in recent years. They are not directed to a “fundamental economic practice”<sup>2</sup> or a method of doing business,<sup>3</sup> nor are they directed to mere organization or manipulation of data<sup>4</sup> or “data in its ethereal, nonphysical form.”<sup>5</sup> There is nothing demonstrably fundamental or age-old about a pharmacist using

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<sup>2</sup> See, e.g., *Alice*, 134 S. Ct. 2356 (finding claims directed to the concept of “intermediated settlement”); *Bilski v. Kappos*, 561 U.S. 593, 611 (2010) (finding claims directed to the concept of “hedging risk”); *OIP Techs.*, 788 F.3d at 1362 (finding claims directed to the concept of “offer-based price optimization”).

<sup>3</sup> *Ultramercial, Inc.*, 772 F.3d at 715 (finding claims directed to the concept of “using advertising as an exchange or currency”); *Accenture Global*, 728 F.3d at 1344 (finding claims directed to the concept of “generating tasks [based on] rules . . . to be completed upon the occurrence of an event”); *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1355 (Fed. Cir. 2014) (finding claims directed to the concept of “creating a contractual relationship”); *DealerTrack*, 674 F.3d at 1333 (finding claims directed to the concept of “processing information through a clearing-house”); *Versata Dev. Group, Inc. v. SAP Am., Inc.*, 2015 U.S. App. LEXIS 11802 (Fed. Cir. July 9, 2015) (finding claims directed to the concept of “determining a price”); *Intellectual Ventures I LLC v. Capital One Bank (USA)*, 2015 U.S. App. LEXIS 11537 (Fed. Cir. July 6, 2015) (finding claims directed to “tracking financial transactions to determine whether they exceed a pre-set spending limit (i.e., budgeting)”; *Bancorp Services v. Sun Life*, 687 F.3d 1266, 1280 (Fed. Cir. 2012) (finding claims directed to “managing a stable value protected life insurance policy by performing calculations and manipulating the results”).

<sup>4</sup> *Content Extraction*, 776 F.3d at 1347 (finding claims directed to the “basic concept of data recognition and storage”); *CyberFone Sys., LLC v. CNN Interactive Group, Inc.*, 558 Fed. Appx. 988, 992 (Fed. Cir. 2014) (finding claims directed to “the well-known concept of categorical data storage”).

<sup>5</sup> *Digitech Image Techs., LLC v. Electronics for Imaging, Inc.*, 758 F.3d 1344, 1350 (Fed. Cir. 2014) (finding claims directed to the concept of a device profile containing color information and spatial information).

various electronic tools to remotely supervise and verify a non-pharmacist's sterile compounding work—and certainly not on the record here.

Prior to Dr. Alexander's invention, sterile compounding could not be supervised or verified remotely, resulting in a situation where errors were sometimes unable to be identified and corrected before the prepared medication was administered to patients. '887 Patent, at 1:14-62. Because the methods reflect the innovative use of a hardware and software system in the pharmacy field, are used to "improve[] an existing technological process" of sterile compounding supervision and verification, and "overcome a problem specifically arising in the realm" of pharmacies, they are not directed to mere abstract ideas. *See Alice*, 134 S. Ct. at 2358; *DDR Holdings*, 773 F.3d at 1257.

The Supreme Court has held that "we must distinguish between patents that claim the 'building blocks' of human ingenuity and those that integrate the building blocks into something more, thereby 'transforming' them into a patent-eligible invention." *Alice*, 134 S. Ct. at 2354 (citations and internal alterations omitted). The methods claimed in the '887 Patent are not attempting to tie up any building blocks of human ingenuity. They purport to claim a specific application of how a pharmacist could remotely supervise and verify a non-pharmacist's sterile compounding work. Because the claims are not directed to an abstract idea, the district court's judgment must be reversed.

B. The Claims Recite a Sufficient Inventive Concept

Step two of the *Alice* framework is “a search for an ‘inventive concept’— i.e., an element or combination of elements that is ‘sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.’” *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 1293). Put another way, step two questions whether the claims are drafted in an “effort designed to monopolize the [abstract idea] itself.” *Id.* at 2357-58.

For claims involving computer-implemented method steps, merely reciting a generic computer component or “[s]tating an abstract idea while adding the words ‘apply it with a computer’” does not satisfy the inventive concept prong. *Alice*, 134 S. Ct. at 2358 (quoting *Mayo*, 132 S. Ct. at 1293). However, a claim that involves a specially-programmed computer, or where generic computer components are used in a manner unconventional for the industry, can demonstrate an inventive concept. *See Mayo*, 132 S. Ct. at 1294; *Alice*, 134 S. Ct. at 2359; *Dealertrack*, 674 F.3d at 1333; *Content Extraction*, 776 F.3d at 1348.

Here, the district court concluded that “the ’887 Patent, as a whole, fails to demonstrate the necessary inventiveness to transform the claimed invention and overcome the fact that the patent’s claims are drawn to an impermissibly abstract idea [i.e., ‘supervision and verification’].” A0012. There are four major errors underpinning this conclusion: (1) the claims recite an inventive concept well

beyond a generic computer implementation of the abstract idea of “supervision and verification,” as the district court held; (2) the district court failed to properly consider extensive un rebutted evidence proving that remote supervision and verification of sterile compounding was unconventional in the relevant field; (3) the use of existing technology in the claimed method does not preclude patent eligibility; and (4) the conclusion, affecting 13 distinct asserted claims, was supported by an analysis only of claim 1, which analysis was itself incomplete and flawed. Each of these errors, all of which prevent the district court’s judgment from being sustained, will now be addressed in turn.

*1. The Claims are Replete With Meaningful Limitations Above and Beyond the Purported Abstract Idea*

The claims of the ’887 Patent do not merely “[s]tat[e] an abstract idea while adding the words ‘apply it with a computer.’” *Alice*, 134 S. Ct. at 2358 (quoting *Mayo*, 132 S. Ct. at 1293). Even if the claims were directed to the abstract concept of “supervision and verification” under *Alice* prong 1 as the district court held, the claims provide considerable technical detail to assure that they were not merely drafted “in an effort designed to monopolize the [abstract idea] itself.” *Alice*, 134 S. Ct. at 2357-58 (quoting *Mayo*, 132 S. Ct. at 1293). The claims are strictly limited to a specific *application* of the concept of supervision and verification. They address a particular technological problem of quality control when a non-pharmacist performs sterile compounding and a pharmacist is not

available on-site to supervise and verify the process. The claims recite “capturing ... one or more images of the pharmacy work ... as the work is being performed by the non-pharmacist person” (and two or more images, each “at a different stage of the compounding,” as specified by claim 16). Once those images are transmitted to the remote pharmacist (and, per claim 1, stored on a website), the sterile compounding process is reviewed and specific indications of correctness are provided by the remote pharmacist and at the institutional pharmacy before the medication is added to pharmacy stock. The verification is accomplished electronically by expressly-recited custom “verification software” that does not exist in any off-the-shelf computer (*see infra*).

The claims are clearly not directed to any and all forms of “supervision and verification,” “remote supervision and verification,” or even “remote supervision and verification of pharmacy functions performed by a non-pharmacist.” These claims encompass a precise, innovative use of hardware and software to accomplish a narrowly-identified technological improvement in the pharmacy industry. The claims are quite specific in this regard, requiring at least the following substantial limitations in applying the purported abstract idea: (1) supervising sterile compounding (2) performed by a non-pharmacist person (3) through use of an image capture device and (4) verification software that (5) provides for transmission and (6) storage of (7) one or more images of sterile

compounding process (8) captured as that process is being performed, and also includes (9) receiving and (10) providing an indication that the pharmacist has in fact verified the same.

These concrete requirements, utilized in the claimed ordered combination of steps, do not preempt any other ways that pharmaceutical supervision and verification—remote or otherwise—might be performed, and the district court found nothing to the contrary. The transmitted images need not be stored on a website, for example, as recited in independent claim 1. The process need not involve capturing “two or more images,” each “at a different stage of the compounding,” as recited in independent claim 16. The process need not capture images that include multiple material components and “one or more measures for the material components, as recited in dependent claims 2 and 17. The process need not have the pharmacist provide verification of the compounding “on a step-by-step basis,” as recited in dependent claims 15 and 27. Remote supervision and verification could even be accomplished using non-visual means, such as gravimetric (i.e., weight-based) measurements taken of the chemical compounds during various steps of the process, which are transmitted to the remote site. *See* A2568-69 (BD arguing that “[y]ou could look at the weight, for example, of the various elements as they’re being prepared to figure out if you actually have the correct amounts and the correct steps are being followed”); *see also* A2113 (Texas

Pharmacy Code providing that “Class A pharmacies compounding sterile pharmaceuticals shall have ... metric-apothecary weight and measure conversion charts”). Even if the claims were directed only to the mere abstract idea of “supervision and verification,” they include so many other meaningful limitations that it cannot be seriously suggested that they were drafted in an effort to monopolize such a concept.

2. *Remote Supervision and Verification of Pharmacy Functions, Especially Sterile Compounding, is Not a Conventional Activity in the Pharmacy Field*

The evidence before the district court did not establish (let alone undisputedly establish for purposes of summary judgment) that the use of computers, cameras, a network, and software combined to perform remote telepharmacy functions was routine or conventional. The best and only evidence alleged to show conventional telepharmacy practices presented by Baxter was the 2001 Texas Pharmacy Code discussed above, which was amended in 2001 to allow, for the first time, only certain limited telepharmacy activities, and not including sterile compounding. A2408-09 (explaining that pre-2001 no remote pharmacy functions were permitted). The claims of the ’887 Patent hardly “read on” the 2001 Texas Pharmacy Code, as Baxter contended—the claims dramatically depart from what the Texas Pharmacy Code ever contemplated at that time. A2040.

A single statute from one forward-thinking state<sup>6</sup> in 2001—only four years prior to the filing of the '887 Patent—hardly establishes that the limited telepharmacy practices permitted in the Texas Pharmacy Code were the kind of “well-understood, routine, [and] conventional activities” required to defeat patent eligibility. *See Content Extraction*, 776 F.3d at 1347-48. And, again, remote supervision and verification of sterile compounding was not even one of those limited activities permitted under the regulations in 2001. A2408-11. Very recently-created documents like the 2001 Texas Pharmacy Code cannot ordinarily establish that something is fundamental, age-old, or conventional. It is more appropriate to support such findings with old (or at least instructional and/or historical) authoritative texts. *See, e.g., Alice*, 134 S. Ct. at 2356 (citing Emery, *Speculation on the Stock and Produce Exchanges of the United States*, in 7 *Studies in History, Economics and Public Law* 283, 346-356 (1896)); *Bilski*, 561 U.S. at 635 (citing D. Chorafas, *Introduction to Derivative Financial Instruments* 75-94 (2008); C. Stickney, R. Weil, K. Schipper, & J. Francis, *Financial Accounting: An Introduction to Concepts, Methods, and Uses* 581-582 (13th ed. 2010); S. Ross, R.

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<sup>6</sup> Texas was one of the first states to implement telepharmacy systems to help service rural areas. *See USA Today, Telepharmacy Project Expands Across Country*, available at [http://usatoday30.usatoday.com/news/health/2008-09-12-virtual-pharmacy\\_N.htm](http://usatoday30.usatoday.com/news/health/2008-09-12-virtual-pharmacy_N.htm) (Sep. 12, 2008) (explaining that “[i]n most cases, pharmacy has more laws and rules than any other area of health care and many states are unwilling to make modifications or adjustments,” and that “[t]he first telepharmacy in Texas opened in 2002 in the town of Turkey, but only a few more have popped up since then”).

Westerfield, & B. Jordan, Fundamentals of Corporate Finance 743-744 (8th ed. 2008)). No such evidence exists in this record.

Beyond the 2001 Texas Pharmacy Code, the next best evidence Baxter offered was a handful of publications showing that, as a general matter, supervision and verification were performed by physicians, lawyers, and teachers. A2039-40. Notably, Baxter identified nothing in these articles that showed any *remote* or electronically-facilitated supervision and verification in those fields, let alone remote supervision in the pharmacy field. *Id.*

In any event, the Texas Pharmacy Code and Dr. Anderson's declaration make clear that using electronic means to remotely supervise and verify sterile compounding, as expressly claimed in the '887 Patent, is decidedly *not* conventional. As discussed above, in the 2001 Texas Pharmacy Code the telepharmacy system was used not to determine whether the medication was properly made, but only "for the provider pharmacist to perform the final check of the prescription medication and authorize the printing of a prescription label at the remote site before the medication was dispensed to the patient." A2409 (citing A2077, at § 291.20(c)(4)(D)(vi) (allowing a "visual check using electronic methods" to confirm whether "the prescription has been dispensed accurately as prescribed")). To the extent that any "image capture" or "store and forward" technology was contemplated for telepharmacy in the 2001 Texas Pharmacy

Code,<sup>7</sup> it was only for a “final [visual] check” that the previously prepared medication matched the prescription, and never in the context of remotely supervising and verifying sterile compounding of the medication. A2076-77, at §291.20(c)(4)(D)(ii), (vi).

Indeed, despite the 2001 telepharmacy amendments, for institutional pharmacies the Texas Pharmacy Code “still required a pharmacist to directly—i.e., on-site and in person—supervise and verify pharmacy functions performed by non-pharmacist persons, including the preparation of medications and particularly the preparation of sterile compounded products.” A2409; A2091-92, at §291.36(c)(4)(B)(ii)(II) (sterile compounding may be performed [at a Class A pharmacy] by a technician only if the technician is “under the direct supervision of and responsible to a pharmacist”); A2092, at §291.36(c)(4)(B)(iii)(IX)(-b-)(-3-) (allowing a pharmacy technician to perform “compounding sterile pharmaceuticals” provided that “the pharmacy technical is supervised by a pharmacist” who conducts both “in-process” and “final” checks). Thus, non-pharmacists performing sterile compounding in Class A pharmacies are still substantially limited in how and when they can perform those activities under the 2001 Texas Pharmacy Code. *Id.* It was not until 2008, following a successful pilot

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<sup>7</sup> See A2072-73, at §291.20(c)(2)(I) (allowing for use of “[a] specific image captured electronically from a video or other image capture device”); A2073, at §291.20(c)(2)(J)) (allowing for use of “[a] video or still image record which is saved electronically for future review”).

project by Dr. Alexander, that the Texas Pharmacy Code was amended to permit remote supervision and verification of sterile compounding. A2410-11 (citing A2441, A2468-69). And even then that permission was limited to institutional pharmacies only at small hospitals having fewer than 100 beds. *Id.*

On this record, the district court's determination that remotely "supervising and verifying the work of a nonpharmacist" is "conventional" and "arguably age-old" cannot stand. A0012. That point is not even "arguabl[e]" (A0012) where none of the evidence supports that conclusion. All the evidence shows that remote supervision and verification of sterile compounding, as reflected by the ordered combination of steps in the '887 Patent, is decidedly *not* conventional. The district court erred by reaching the contrary conclusion and its judgment should be reversed.

To be clear, the novelty of the components used to practice the claimed method does not affect the § 101 analysis. *See Bilski*, 561 U.S. at 620; *Diehr*, 450 U.S. at 188-189. As demonstrated *infra*, the use of existing technology does not alone defeat patent eligibility for a claimed *method of using* that technology. But the fact that a claimed method reflects an innovative use of that existing technology can and should rebut a contention that the method involves only conventional activity in the field, as is the case here.

At a minimum, the evidence presented by BD raises a genuine dispute of material fact rendering summary judgment improper. While patent eligibility under § 101 is an issue of law, “[t]his legal conclusion may contain underlying factual issues” and “[a]lmost by definition, analyzing whether something was ‘conventional’ or ‘routine’ involves analyzing facts.” *Accenture Global*, 728 F.3d at 1341; *Ultramercial*, 722 F.3d at 1339. On summary judgment, where “[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor,” the facts surrounding the 2001 Texas Pharmacy Code, Dr. Alexander’s pilot project, and the subsequent 2008 amendment to the Texas Pharmacy Code have at least carried BD’s burden to create a triable issue. *Anderson*, 477 U.S. at 255. Proper consideration of this evidence would have resulted in the denial of Baxter’s summary judgment motion, and would have obligated the district court to allow the issue of conventionality to be resolved by a jury at trial.

3. *Using Existing Technology to Perform the Method Does Not Defeat Patent Eligibility*

The district court’s judgment hinges largely on its finding that the claimed invention utilizes existing computer, network, and camera components that are not “in themselves new inventions.” A0012. From this premise, the district court deems the entirety of the claimed methods “seek[ing] merely to apply existing technology to the abstract and arguably age-old process of supervising and

verifying the work of a nonpharmacist.” *Id.* The district court never circled back to examine whether the elements, not individually but as an ordered combination, reflected an inventive concept under *Alice*, which is itself error.

Although the '887 Patent may disclose that the claimed image capturing may be done by an “off-the-shelf” digital camera, and utilizing the existing Internet and a “general-purpose computer system” ('887 Patent, at 6:11-16, 4:16-17, 16:4-7), there is no per se rule requiring that all components recited in a method claim “in themselves be new inventions” to satisfy § 101. Yet the district court’s reasoning was heavily based on this sentiment and other similar improper notions. *See* A0011 (finding that “[t]he patent does not describe a novel sterile compounding process, a new type of image-capture device, or a particularized website or software program to perform any step”). Such a novelty-based element-by-element approach has been squarely rejected by the Supreme Court. *See Bilski*, 561 U.S. at 620 (“‘[T]he proper construction of § 101 ... does not involve the familiar issu[e] of novelty’ that arises under § 102.”) (Stevens, J., concurring) (quoting *Parker v. Flook*, 437 U.S. 584, 588 (1978)); *Diehr*, 450 U.S. at 188-189 (“The ‘novelty’ of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.”); *id.* (“[A] new combination of steps in a process may be patentable even though all the

constituents of the combination were well known and in common use before the combination was made.”).

Whether a claimed computer system or process is “well-known, routine, and conventional” depends largely on the usage of those computer components or processes in the industry that is the subject of the patent at issue—not in the computer industry more generally. *See Mayo*, 132 S. Ct. at 1299 (explaining that reciting “well-understood, routine, conventional activity, previously engaged in by those *in the field*” cannot demonstrate an inventive concept); *Alice*, 134 S. Ct. at 2359 (finding no inventive concept for “computer functions are ‘well-understood, routine, conventional activit[ies]’ previously known *to the industry*”) (emphases added). A contrary rule would mean that *no* inventions using existing computer technology could be patent-eligible except those that reinvent a computer or provide it with some special novel programming, and that cannot be right. *See Diehr*, 450 U.S. at 188-189; *cf. KSR*, 550 U.S. at 418-19 (“[I]nventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.”). Indeed, in *Alice* the Supreme Court noted that improving computer technology was only one of multiple ways an inventive concept could be demonstrated in a computer-implemented invention. *Alice*, 134 S. Ct. at 2359 (“The method claims do not, for example, purport to improve the functioning of

the computer itself. ... Nor do they effect an improvement in *any other technology or technical field.*”) (emphasis added).

*Diehr* is instructive, and confirms that one can use, but not reinvent, a computer and still cross the § 101 threshold. In *Diehr*, the claimed invention utilized an existing computer to perform calculations under a “well-known mathematical equation” in connection for a process for curing rubber. *Diehr*, 450 U.S. at 187. Basically, the computer used the equation to make calculations that determined when the rubber mold should be opened to avoid overcuring or undercuring the rubber. *Id.* To be clear, rubber could be cured just as well without a computer, but the use of a computer improved the reliability of the process. *Id.* (“[O]ne does not need a ‘computer’ to cure natural or synthetic rubber, but if the computer use incorporated in the process patent significantly lessens the possibility of ‘overcuring’ or ‘undercuring,’”). What *Diehr* had invented, in essence, was the use of a computer for better quality control over an existing rubber curing process. Because the result was an improvement to the rubber curing process, the claims were deemed a patent eligible “*application ... of a mathematical formula.*” *Id.* at 187-88 (emphasis in original); *see also Alice*, 134 S. Ct. at 2358 (“[T]he claims in *Diehr* were patent eligible because they improved an existing technological process, not because they were implemented on a computer.”).

Much like *Diehr*, the '887 Patent provides a new method that improves the sterile compounding process by using computer components to accomplish quality control for that process in a better way. It makes no difference whether Dr. Alexander's invention created a new computer or camera technology in the process. As the Court explained in *Diehr* when recounting why method claims are distinctly patentable from apparatus claims, "[t]he machinery pointed out as suitable to perform the process may or may not be new or patentable; whilst the process itself may be altogether new, and produce an entirely new result. The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence.'" 450 U.S. at 183-84 (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-788 (1877)). The district court's insistence that the software and hardware tools that are combined to perform the patented method in the claimed manner be individually novel was error. Although BD believes that the combined software and hardware is itself also an innovative tool, the processes claimed are demonstrably innovative and non-conventional in the relevant field. Whether viewed as a completely new method or an improvement over existing methods, this is enough to cross the § 101 threshold.

In any event, to the extent the use of off-the-shelf components is viewed as relevant to the inquiry, the district court overlooked the fact that the claimed

“verification software” is disclosed as involving “custom” programming and “a custom protocol” that can be coded into a general-purpose computer, but is not an off-the-shelf function of such computers. *See* A2390, A2391, A2402 (BD arguing that the verification software makes the computer “specially-programmed”). The ’887 Patent discloses several ways in which the custom coding may be accomplished. *See, e.g.*, ’887 Patent, at 9:38-43 (“For example, the institutional pharmacy site and the remote pharmacist site may be connected over the Internet via a custom protocol for viewing remote pharmacy work, such as may be implemented by remote verification software 140.”); *id.* at 14:66-15:5 (“[C]ustom software, such as remote verification software 140, configured specifically for communication and data exchange as part of remote verification of pharmacy functions may provide a user interface for uploading, downloading, and/or reviewing images stored on server 700.”); *id.* at 15:28-32 (“[S]erver 700 may implement a messaging interface allowing custom software for remote verification of pharmacy functions, such as remote verification software 140, to send messages requesting the storage or retrieval of images, documents or other data.”). This custom computer functionality, although not required to cross the § 101 threshold, further confirms the presence of an inventive concept. *Alice*, 134 S. Ct. at 2359 (finding no inventive concept in individual claim elements because “each step does no more than require a generic computer to perform generic computer functions”).

The use of such custom software in the claimed methods cannot be deemed “conventional” in the relevant pharmacy field. *See Mayo*, 132 S. Ct. at 1294; *Alice*, 134 S. Ct. at 2359; *Dealertrack*, 674 F.3d at 1333; *Content Extraction*, 776 F.3d at 1348. At the very least, this raises a genuine issue of material fact concerning whether the claimed system included a specially-programmed computer to overcome *Alice* prong 2.

Finally, in reaching its contrary conclusion, the district court also distinguished this Court’s decision in *DDR Holdings*, reasoning that Dr. Alexander’s invention did not ““overcome a problem specifically arising in the realm of computer networks’ or, in this case, the pharmacy industry.” A0012 (citing *DDR Holdings*, 773 F.3d at 1257). But this finding is directly controverted by the evidence, which shows that the invention does solve the pharmacy-centric problem of needing supervision and verification of sterile compounding by a pharmacist who may be remote in time or place from the pharmacy technician. ’887 Patent, at 1:14-62; A2408-09. BD was entitled to have this unrebutted evidence viewed in the light most favorable to it, and summary judgment should not have been entered in the presence of this evidence.

4. *No Separate Analysis for Each Disputed Claim was Conducted by the District Court to Support the Invalidity Judgment*

The district court only examined claim 1 in full. It quoted but did not analyze claim 16 separately, and held that eleven dependent claims were drawn to

ineligible subject matter with no more than the single conclusory sentence asserting that those claims “do not change the validity calculus.” A0004. This cursory mention is contrary to the Supreme Court’s repeated instruction that claims are to be considered individually, and each as a whole. *See Alice*, 134 S. Ct. at 2355; *Diehr*, 450 U.S. at 188.

Where the parties dispute whether a claim is representative and whether other claims stand and fall with the allegedly representative claim, district courts cannot find other claims invalid without a separate analysis for each claim to show that the claims are not patentably distinct. *See Content Extraction*, 776 F.3d. at 1348 (permitting treatment of “representative claim” where patentee “never asserted ... that the district court should have differentiated any claim from those identified as representative,” “[n]or did [the patentee] identify any other claims as purportedly containing an inventive concept”). While it might be proper to dispose of dependent claims that admittedly rise or fall with an independent claim pre-issuance, given the presumption of validity for issued patents, “that rule has no application in a district court proceeding to determine whether the claims of an issued patent are valid.” *Shelcore, Inc. v. Durham Indus.*, 745 F.2d 621, 624-25 (Fed. Cir. 1984) (“[A] party challenging the validity of a claim, absent a pretrial agreement or stipulation, must submit evidence supporting a conclusion of invalidity of *each* claim the challenger seeks to destroy.”) (emphasis in original).

The district court's reliance on *Content Extraction* to excuse its failure to consider the claims individually was therefore incorrect. Here, Baxter and BD made separate arguments as to distinct claims, and it was improper to invalidate all the claims without a separate analysis for each claim. *See* A2045; A2393-94.

The distinct claims in the '887 Patent all additionally define the invention in ways that represent still more specific and practical applications of the invention above and beyond the requirements analyzed in detail above. Independent claim 16 expressly requires the capturing of "two or more images" of the sterile compounding process, each, "captured at a different stage" of the process. Dependent claims 2 and 17, for example, recite the particular content of the captured image(s) of the sterile compounding process as including multiple material components and "one or more measures for the material components." Similarly, dependent claims 15 and 27 require that the remote pharmacist provides verification to the non-pharmacist regarding the compounding "on a step-by-step basis."

Each and every one of these claims further focuses the method on the particular pharmacy-centric problem being solved, and further limits the claims to recite steps applicable to that specific context. The district court did not analyze these claims "with less detail" as it purported (A0004), but instead it included no detail whatsoever even though the parties separately argued those claims. *See*

A2045; A2393-94. As such, the district court does not acknowledge that these additional steps and structures make the claimed methods more concrete and evidence a more specific inventive concept than the primary claim requirements discussed above.

The district court also did not appreciate that, as with the elements common to claims 1 and 16, no evidence exists in the record to show that these additional features were routine or conventional in the pharmacy field. Without specific findings, let alone a record to support such findings, these additional claims cannot be deemed ineligible on summary judgment. Although none of these claims are directed to ineligible subject matter as explained above concerning the claim elements common to claims 1 and 16, the district court's judgment as to all claims other than claim 1 cannot stand for these additional reasons.

### **CONCLUSION**

For the foregoing reasons, the judgment that all asserted claims of the '887 Patent are directed to patent-ineligible abstract ideas should be reversed and remanded so that the case may proceed to trial.

Respectfully submitted,

Dated: October 13, 2015

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**ADDENDUM**

1. Final Judgment dated August 3, 2015 (A0001)
2. Order Granting Motion for Summary Judgment dated August 3, 2015 (A0002 – A0013)

Case 1:14-cv-00222-LY Document 66 Filed 08/03/15 Page 1 of 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS,  
AUSTIN DIVISION

**FILED**

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BECTON, DICKINSON AND  
COMPANY,  
PLAINTIFF AND  
COUNTER-DEFENDANT,

V.

BAXTER INTERNATIONAL, INC.,  
 DEFENDANT  
 AND COUNTER-PLAINTIFF.

CAUSE NO. 1-14-CV-222-LY

## FINAL JUDGMENT

Before the court is the above-styled and numbered cause. By separate order signed this day, the court granted Defendant Baxter International Inc.'s ("Baxter") Motion for Summary Judgment of Invalidity Based on 35 U.S.C. § 101 (Clerk's Doc. No. 47). The court concluded that the asserted claims of United States Patent Number 8,374,887 are invalid because the claims are drawn to unpatentable subject matter. *See* 35 U.S.C. § 101. Because the claims are invalid, nothing remains for determination in this case. Accordingly, the court renders the following Final Judgment pursuant to Federal Rule of Civil Procedure 58.

**IT IS HEREBY ORDERED** that Plaintiff Becton, Dickinson and Company **TAKE**  
**NOTHING** by its action against Defendant Baxter International, Inc.

**IT IS FURTHER ORDERED** that Baxter is awarded costs of court.

**IT IS FINALLY ORDERED** that this case is **CLOSED**.

SIGNED this 3rd day of August, 2015.

LEE YEAKEL  
UNITED STATES DISTRICT JUDGE

## CONCLUSIONS

## I. BACKGROUND

Plaintiff Becton, Dickinson and Company (“Becton”)<sup>1</sup> brings this suit against Defendant Baxter International, Inc. (“Baxter”), alleging infringement of United States Patent No. 8,374,887 (the “‘887 Patent”). Baxter contends that the asserted claims of the ‘887 Patent are invalid under Chapter 35, United States Code Section 101 (“Section 101”) for failing to claim patentable subject matter. Specifically, Baxter contends that the asserted claims are directed to the abstract idea of “supervision and verification,” and that the addition of “generic technology claimed to implement the abstract idea” fails to provide the required “inventive concept” necessary to “transform the claimed abstract idea into a patent-eligible application.” *Alice Corp. Pty. Ltd. v. CLS Bank, Int’l*, 134 S. Ct. 2347, 2358 (2014).

In addition to opposing the motion on substantive grounds, Becton argues that this court should postpone judgment on Baxter’s motion until after claim construction.<sup>2</sup> The court disagrees. “Although the determination of patent eligibility requires a full understanding of the basic character of the claimed subject matter, claim construction is not an inviolable prerequisite to a validity determination under § 101.” *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass’n*, 776 F.3d 1343, 1349 (Fed. Cir. 2014) (citing *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 714-15 (Fed. Cir. 2014)); *Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.)*, 687 F.3d

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<sup>1</sup> On December 9, 2014, this court granted Becton’s unopposed motion to substitute Becton for inventor and original Plaintiff Emily H. Alexander. Effective October 24, 2014, Becton acquired “all right, title, and interest” to the patent-in-suit and the “sole and exclusive right to replace Alexander as the Plaintiff and Counter-Defendant in this litigation.”

<sup>2</sup> The parties’ claim-construction briefing, joint corrected claim-construction statement, and Baxter’s notice of intervening claim-construction authority are also before the court. Additionally, the court held a claim-construction hearing on November 24, 2014. The court is familiar with the parties’ claim-construction positions and disputed claim terms.

1266, 1273–74 (Fed. Cir.2012) (finding that district court did not err by declaring claims patent-ineligible at pleading stage without first construing claims or allowing parties to conduct fact discovery and submit opinions from experts supporting their claim-construction positions). The court concludes that the asserted claims are drawn to an abstract idea, and there is no reasonable construction of any term that would bring these claims within the bounds of patentable subject matter. Therefore, this court’s Section 101 analysis is appropriate at this stage of the litigation.

#### A. The ‘887 Patent

According to the abstract, the ‘887 Patent is generally directed toward “a method and a system for remotely supervising and verifying technical pharmacy functions performed by a non-pharmacist located in an institutional pharmacy.” The invention is summarized as “providing certain pharmacy services to institutionalized patients at an institution where a live pharmacist is not available” such that an “institutional pharmacy and a remotely located pharmacist are linked via wired or wireless telecommunication systems in a manner that enables the pharmacist to remotely supervise and verify that pharmacy functions are properly performed by non-pharmacist personnel.” ‘887 Patent 2:13-20.

Claim 1 of the ‘887 Patent is representative for the purposes of the court’s Section 101 analysis:<sup>3</sup>

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<sup>3</sup> Having thoroughly reviewed the ‘887 Patent and all of its associated claims, the court agrees with Baxter that Claim 1 is representative. Where claims are “substantially similar and linked to the same abstract idea,” the court may dispose of the other claims in the patent with less detail. *Content Extraction & Transmission, LLC v. Wells Fargo Bank, Nat’l Ass’n*, 776 F.3d 1343, 1348 (Fed. Cir. 2014). Despite Becton’s arguments to the contrary, the dependent claims of the ‘887 Patent introduce only slight variations of the independent claims, variations which do not change the validity calculus; thus the court need not consider each claim distinctly. *See Id.* at 1349 (“[W]hile

1. A method for remote supervision and verification of pharmacy functions that are performed by a non-pharmacist person, comprising:

in response to performance, by a non-pharmacist person, of pharmacy work to prepare a medication at an institutional pharmacy, wherein the pharmacy work requires pharmacist verification of the pharmacy work, wherein performing the pharmacy work comprises the non-pharmacist person performing, at a workstation in the institutional pharmacy, a sterile compounding process to prepare the medication, wherein the medication is compounded from a plurality of material components at the workstation within the institutional pharmacy:

capturing, via an image capture device at the workstation in the institutional pharmacy, one or more images of the pharmacy work performed by the non-pharmacist person as the work is performed by the non-pharmacist person at the institutional pharmacy, wherein at least one of the images is an image of the sterile compounding process performed by the non-pharmacist person that requires verification by a pharmacist for medications to be placed into pharmacy stock;

implementing verification software, via one or more computers at the institutional pharmacy, to remotely verify the work performed by the non-pharmacist person, wherein remote verification of the work performed by the non-pharmacist person comprises:

transmitting the one or more images captured by the image capture device of the sterile compounding process performed by the non-pharmacist person at the workstation to a remote pharmacist for review, wherein said transmitting the one or more images comprises storing the images on a website; receiving an indication of the remote pharmacist's verification of the correct performance of the sterile compounding process by the non-pharmacist person; and

providing, in response to the indication of the remote pharmacist's verification, an indication at the institutional pharmacy that the

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[the dependent] claims may have a narrower scope than the representative claims, no claim contains an 'inventive concept' that transforms the corresponding claim into a patent-eligible application of the otherwise ineligible abstract idea."); see also *Planet Bingo, LLC v. VKGS LLC*, 576 F. App'x 1005, 1007 (Fed. Cir. 2014) (unpublished decision).

remote pharmacist has verified the sterile compounding process performed by the non-pharmacist person.

‘887 Patent 17:37-18:10. Independent Claim 16, the only other independent claim in the ‘887 Patent, recites the elements of Claim 1, with the exception of the images stored on a website, and adds one additional requirement:

wherein capturing the one or more images comprises capturing two or more images of the sterile compounding process of the sterile compounded medications as the sterile compounded medications are prepared, wherein at least one of the two or more images is captured at a different stage of the compounding of the sterile compounded medications than at least one other of the two or more images;

*Id.* at 19:38-45.

## II. DISCUSSION

Under Federal Rule of Civil Procedure 56(a), summary judgment may be granted only if all the submissions of the parties taken together “show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (internal citation and quotation marks omitted); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). The moving party bears the initial burden of demonstrating “the absence of a genuine issue of material fact.” *Celotex*, 477 U.S. at 323. Mere conclusory allegations are not competent summary judgment evidence and are insufficient to defeat a motion for summary judgment. *Eason v. Thaler*, 73 F.3d 1322, 1325 (5th Cir.1996). A court must draw all reasonable inferences in favor of the nonmoving party. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir.2007).

“Whether a claim is drawn to patent-eligible subject matter under [Section] 101 is a threshold inquiry[.]” *In re Bilski*, 545 F.3d 943, 950 (Fed. Cir. 2008) (“*Bilski I*”), *affirmed sub nom. Bilski v.*

*Kappos*, 561 U.S. 593 (2010) (“*Bilski I*”). If a claim is not drawn to patent-eligible subject matter, it “must be rejected even if it meets all the other legal requirements of patentability.” *Id.* The determination of whether a claim is drawn to patent-eligible subject matter is a pure question of law. See *Fort Properties, Inc. v. Am. Master Lease LLC*, 671 F.3d 1317, 1320 (Fed. Cir. 2012); see also *Bilski I*, 545 F.3d at 951 (explaining that patent validity under Section 101 is “issue of law”).

Section 101 of the Patent Act defines patentable subject matter: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101. However, Section 101 also “contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable.” *Alice*, 134 S. Ct. at 2354 (internal quotations and citation omitted). “[T]he concern that drives this exclusionary principle [is] one of pre-emption.” *Id.* (citing *Bilski II*, 561 U.S. at 611).

The Supreme Court has stressed the need to “tread carefully in construing this exclusionary principle lest it swallow all of patent law. At some level, all inventions embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept.” *Alice*, 134 S. Ct. at 2354 (internal citations omitted).

In order to guide courts in this inquiry, the Supreme Court established a “framework for distinguishing patents that claim . . . abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, ‘what else is there in the claims before us?’ . . . to determine whether the additional elements ‘transform the nature of the claim’ into a patent-eligible

application.” *Id.* at 2355 (internal citations omitted). Step two of the analysis is a “search for an ‘inventive concept’—i.e., an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.” *Id.* (internal quotations and citations omitted).

#### **A. Application of the Two-Step *Alice* Framework to the ‘887 Patent**

Broadly speaking, Baxter argues that all the asserted claims of the ‘887 Patent fall outside Section 101 eligibility because they teach the “abstract ideas of ‘supervision’ and ‘verification’ of pharmacy functions.” According to Baxter, “[s]upervision and verification are even more fundamental ‘building blocks of human ingenuity’ than the ‘intermediated settlement’” patent which was found patent ineligible in *Alice*. Moreover, Baxter argues, the ‘887 Patent’s “addition of ‘off-the-shelf’ technology does not add the required inventive concept” necessary in a Section 101 analysis. Baxter argues that none of the method steps contain the required inventive concept “in the physical realm of things” necessary to transform an abstract idea into a patent-eligible invention. Baxter asserts that “[t]aken individually and as a whole, the independent claims do nothing more than recite a series of conventional steps carried out using basic camera and computer functions.” Finally, Baxter argues that the patent’s field-of-use limitation of “sterile compounding for medications to be placed into pharmacy stock” is not transformative and does not render the claims patent eligible.

In response, Becton argues that the claims are not merely directed at the abstract concept of supervision and verification because they recite additional “substantial structural elements” and “particularized implementations of the inventive concept in a specific sequence.” Becton contends

that Baxter's characterization of the thrust of the patent is oversimplified and that the claims go "far beyond the bare concepts of 'supervision and verification.'" Becton also argues that the '887 Patent is not abstract because the Supreme Court has limited the abstractness inquiry to "only . . . a handful of subject matter areas . . . including implementing purely mental activities, mathematical or economic principles, business practice, or algorithms on a generic computer." Thus, contends Becton, because the '887 Patent's claims recite "hardware components," the subject matter of the '887 Patent "goes far beyond 'simply stat[ing] the [abstract idea] while adding the words 'apply it.'"' (Becton's citations omitted). The crux of Becton's argument, therefore, is that "the claims of the '887 Patent, when considered as a whole, reflect a specific application of a remote sterile compounding supervision and verification process, not impermissibly abstract fundamental concepts or longstanding practices."

Becton further argues that, even if the claims encompass an abstract idea, they also "add 'significantly more' and provide an 'inventive concept.'" Becton contends that Baxter's motion ignores material limitations which "reflect a significant inventive concept" beyond supervision and verification. Becton also argues that Baxter's motion "fails to consider the claim elements as an ordered combination" and urges the court that the '887 Patent's claims are eligible because they "do[] not preempt use of those abstract ideas generally or in the field of pharmacy." In essence, Becton argues that the patent is directed only to *remote* supervision and verification, not supervision and verification as a generalized concept throughout the pharmacy industry.

### 1. The '887 Patent's Claims are Directed Toward a Patent-Ineligible Concept

Despite Becton's vigorous argument that the claims' "structural elements" and "particularized implementations" show that the '887 Patent is not directed at an abstract idea, the court disagrees. After stripping away the technicalisms and superfluous verbiage from the claims' language,<sup>4</sup> it is evident that the gist of the claims, and indeed the entire aim of the patent, involves a pharmacist supervising and verifying the work of a nonpharmacist to ensure the work's accuracy. The steps delineated in the claim describe a particular way of performing this process, but, at base, the claims are directed to this core idea. The "capturing" of an image, "implementing" verification software, "transmitting" the image, and "providing" an indication that the process has been verified are merely steps in the supervision and verification process; the claims do not present a concept or idea that is any more concrete than supervision and verification. It is undeniable that supervision and verification of a nonpharmacist's work is an abstract idea, one that amounts to a fundamental concept and longstanding practice of organizing human behavior applicable to many fields, one of which is pharmacy. The fact that the pharmacist is "remote" is of no added consequence to the abstract nature of the concept. Thus, the court concludes that, because the '887 Patent's claims are drawn to an abstract concept—supervision and verification—the patent is ineligible under the first step of the *Alice* inquiry.

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<sup>4</sup> The '887 Patent's prolix claims exemplify an overly obtuse style of drafting which is all too common in many of the patents this court reviews.

## 2. No Additional Elements are Sufficient to Transform the Nature of the Claims

Under the second step of the *Alice* inquiry, even if a patent attempts to claim an otherwise abstract idea, the claim can be transformed into something patentable if it incorporates an inventive concept, defined by the Supreme Court as “an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.” *Alice*, 134 S. Ct. at 2355.

Becton urges the court that the claims’ additional limitations and the unique ordered combination of these limitations constitute an inventive step that transforms the claim from abstract to patentable. Specifically, Becton characterizes the inventive limitations of Claim 1 to be “(1) supervising sterile compounding (2) performed by a nonpharmacist person (3) through use of an image capture device and (4) verification software that (5) provides for transmission and (6) storage of (7) one or more images of sterile compounding process (8) captured as that process is being performed, and also includes (9) providing an indication that the pharmacist has in fact verified the same.”

The court disagrees. Becton argues that the patent recites hardware components “such as an image capture device and a computer running specially-programmed software” to perform the claimed invention. Examining the claims closely, as both containing individual elements and as an ordered combination, it is inescapable that the claims use generic, off-the-shelf technology applied in a conventional way to achieve the aim of the patent. The patent does not describe a novel sterile compounding process, a new type of image-capture device, or a particularized website or software program to perform any step. The claims and specification instead teach well-known elements used in conventional ways combined to perform the steps of supervision and verification. The court can


find no inventive concept in any of the claim language that “amounts to significantly more” than a detailed description of conventional, if generic, steps of remotely supervising and verifying the work of a nonpharmacist who is preparing prescriptions. *Id.*

Becton does not, and cannot, argue that the computer elements, capture device, network infrastructure, or supporting software described in the claims are in themselves new inventions. Although the elements’ use in the “remote pharmacy” setting is characterized by Becton as a breakthrough, the actual technological components are described only in generic terms, the technical details of which are not described. “Wholly generic computer implementation is not generally the sort of additional feature that provides any practical assurance that the process is more than a drafting effort designed to monopolize the abstract idea itself.” *Alice*, 134 S. Ct. at 2350-51. Becton’s reliance on *DDR Holdings, LLC v. Hotels.com, L.P.* is misplaced; Becton cannot convincingly argue that the ‘887 Patent “overcome[s] a problem specifically arising in the realm of computer networks” or, in this case, the pharmacy industry. 773 F.3d 1245, 1257 (Fed. Cir. 2014). Rather than having created a technological innovation, the patent seeks merely to apply existing technology to the abstract and arguably age-old process of supervising and verifying the work of a nonpharmacist.

Accordingly, the court concludes that the ‘887 patent, as a whole, fails to demonstrate the necessary inventiveness to transform the claimed invention and overcome the fact that the patent’s claims are drawn to an impermissibly abstract idea.

**IT IS THEREFORE ORDERED** that Defendant Baxter International Inc.'s Motion for Summary Judgment of Invalidity Based on 35 U.S.C. § 101 (Clerk's Doc. No. 47) is **GRANTED**. The '887 Patent claims asserted in this action are **INVALID** under Chapter 35, United States Code Section 101.

SIGNED this 3rd day of August, 2015.

  
LEE YEAKEL  
UNITED STATES DISTRICT JUDGE

**CERTIFICATE OF SERVICE**

This is to certify that on October 13, 2015, copies of the foregoing Brief of Plaintiff-Appellant was served on counsel for Plaintiff-Appellee via the Court's ECF system and via electronic mail upon the following:

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**CERTIFICATE OF COMPLIANCE**

Pursuant to Fed. R. App. P. 32(a)(7)(C), I hereby certify that the body of this brief, beginning with the Jurisdictional Statement on page 1, and ending with the last line of the conclusion on page 55, including headings, footnotes, and quotations, is presented in Times New Roman 14-point font and contains 12,664 words, in compliance with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i).

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